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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M–0045, 2003M–0122, 2003M–0010, 2003M–0040, 2003M–0086, 2003M–0116, 2003M–0049, 2003M–0070, 2003M–0011, 2003M–0046, 2003M–0114, 2003M–0115]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA revised 21 CFR 814.44(d) and 814.45(d) (63 FR 4571) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information to FDA's home page at *http://www.fda.gov* on the Internet. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2003, through March 31, 2003. There were no denial actions during

this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

Table 1.—List of Safety and Effectiveness Summaries for Approved PMAs Made Available January 1, 2003, through March 31, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P990071/03M–0045	Biosense Webster, Inc.	STOCKERT 70 RF GENERATOR FOR CARDIAC ABLATION	May 31, 2000.
P980048/03M–0122	Sulzer Spine-Tech	BAK/CERVICAL (BAK/C) INTERBODY FUSION SYSTEM	April 20, 2001
P990065/03M–0010	Sirtex Medical, Inc.	SIR-SPHERES	March 5, 2002.
P010002/03M–0040	United States Surgical Corp.	INDERMIL TISSUE ADHESIVE	May 22, 2002.
P010041/03M–0086	Edwards Lifesciences, LLC	CARPENTIER-EDWARDS S.A.V. BIOPROSTHESIS, MODEL 2650 (AORTIC)	June 24, 2002.
P020009/03M–0116	Boston Scientific, Scimed, Inc.	EXPRESS/EXPRESS 2 MONOTRAIL AND OVER THE WIRE CORONARY STENT SYSTEMS	September 11, 2002.
P010068/03M–0049	Biosense Webster, Inc.	NAVISTAR DS/CELSIUS DS DIAGNOSTIC ABLATION CATHETERS, STOCKERT 70 GENERATOR, AND CATHETER INTERFACE CABLES	September 27, 2002.
P020011/03M–0070	Gen-Probe, Inc.	VERSANT HCV RNA QUALITATIVE ASSAY	November 7, 2002.
P020008/03M–0011	Karl Storz Endoscopy-America	KARL STORZ AUTOFLUORESCENCE SYSTEM	December 12, 2002.
P020027/03M–0046	Dade Behring, Inc.	DIMENSION FPSA FLEX REAGENT CARTRIDGE AND DIMENSION T/F PSA CALIBRATOR FOR DIMENSION RXL AND XPAND SYSTEMS	January 24, 2003.
P800022(S50)/03M–0114	Inamed Corp.	COSMODERM 1 & COSMOPLAST HUMAN-BASED COLLAGEN	March 11, 2003.
P010065/03M–0115	E Med Future	NEEDLE ZAP	March 14, 2003.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: 10/6/03
October 6, 2003.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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